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Royal Australian College of General Practitioners

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23 May 2025

Professor Jeff Dunn AO
Prostate Cancer Foundation of Australia
PO Box 499
St Leonards NSW 1590
via email: research@pcfa.org.au

Dear Prof Dunn AO,

Re: Public Consultation: Draft 2025 Clinical Guidelines for the Early Detection of Prostate Cancer

The Royal Australian College of General Practitioners (RACGP) thanks the Prostate Cancer Foundation of Australia (PCFA) for the invitation to provide comment on the *Draft 2025 Clinical Guidelines for the Early Detection of Prostate Cancer.* The RACGP is the peak body representing Australia's 50,000 general practitioners (GPs) and those working towards becoming a GP. For more than 60 years, we've supported the backbone of Australia's health system by setting the standards for education and practice and advocating for better health and wellbeing for all Australians.

The role of GPs in the early detection of prostate cancer

GPs play an important role in the early detection of all types of cancer, including prostate cancer. GPs are often the first health professional a man will speak to about , prostate cancer screening. Around 79% of males aged 15 and over visited their GP every year.[1] The proportion increases as age increases with 62% of males aged 15–24, compared to 95% of males aged 65 and over, having seen a GP in 2021-22.[1]

GPs undertaking a careful shared decision making process with asymptomatic men is a crucial part of the GP role, explaining the potential benefits and harms of screening. For men who have been diagnosed with prostate cancer, GPs often manage and coordinate their ongoing care. GPs also provide care for those who have been overdiagnosed, and experienced harms as a result.

The RACGP provides recommendations on prostate cancer screening in a number of clinical guidelines, including:

- Guidelines for preventive activities in general practice (the Red book)
- The RACGP & NACCHO National guide to preventive healthcare for Aboriginal and Torres Strait Islander people
- Prostate cancer patient information sheet (due to be updated by end of 2025)

The RACGP commends the PCFA for their hard work in updating these important and valuable clinical guidelines. We provide comment on the consultation questions below.

1. Do you have any feedback on the Guideline Introduction?

1.1 Introductory paragraph (page 1)

Recommended addition: Include cost and morbidity of prostate cancer overdiagnosis

The guideline introduction makes an assumption that the cost of managing advanced disease will be reduced due to early prostate cancer diagnosis. While this is a reasonable assumption, the introductory paragraph should include there is a financial cost as a result of overdiagnosis (to both the health system and to patients), harms, and morbidity. This addition will clarify to readers that careful consideration needs to be

made between the GP and patient to reduce the risk of a variety of harms from both potential advanced disease and potential overdiagnosis.

1.2 Reducing risks of death (page 2)

Recommended addition: include additional information about increased survival and mortality benefit
The PCFA should consider re-wording some of the statements about early detection and increased survival and mortality benefit on page 2 of the draft guideline. These statements should be qualified with additional information that increased survival and mortality benefit numbers do not include people who have been overdiagnosed with prostate cancer, who would have survived without the diagnosis. This addition will provide further context of what these numbers mean for the readers of the guideline.

1.3 Reducing harms

Recommended addition: highlight the guideline recommendations to reduce patient harms

The guideline introduction should include a short paragraph highlighting the guideline also includes recommendations to reduce the harms from detecting and treating clinically insignificant prostate cancer. This is an important part of the guideline and screening process the PCFA may wish to highlight for readers.

1.4 Plain English summary – Why is early detection important? (pages 3-4)

Recommended change: discuss absolute benefits instead of relative risk reduction

The PCFA should consider discussing absolute benefits rather than relative risk reduction and survival statistics. The RACGP is concerned use of absolute benefits may exaggerate the benefits and create confusion for readers. We recommend stating: for every 1000 men at average risk who chooses to engage in prostate cancer screening, screening will save XX lives over the next 16 years (interpreting the data in the ERSPC trial). This will provide important context for GPs as part of their decision making conversations with patients.

Recommended addition: discuss nuances of potential mortality benefit

The PCFA guidelines are the ideal resource to discuss the nuances of the potential mortality benefit of prostate cancer screening. The potential mortality benefit is still unclear, but needs to be communicated to patients.

- By 11 years, it is approximately 1 man saved from dying of prostate cancer per 1000[2]
- By 16 years, it is approximately 2 men saved from dying of prostate cancer per 1000[3]
- After 25 years, modelling suggests this number may be about 4 per 1000[4]
- After 40 years, modelling suggests this number may be about 14 per 1000 when starting screening from age 50[5]

This data indicates some men may experience early side effects for mortality benefits which may take a long time to occur. For men making a decision later in life where the 40 year benefits may have little relevance. A brief explanation of these nuances in screening would be helpful for shared decision making with patients.

2. Do you have any feedback on the Executive Summary?

2.1 General feedback on the Executive Summary

Recommended addition: a list of screening tests that are not recommended

It would be helpful to have a list of prostate cancer screening tests that are not recommended so readers can quickly identify these.

Recommended addition: a summarised list of harms from overdiagnosis and treatment

A summary list of the potential harms from overdiagnosis and from prostate cancer treatment would provide readers with key information to convey to their patients as part of the decision making process. Patients often like to know the likelihood of side effects or harms before making a decision. This should include information such as:

- rates of impotence
- rates of incontinence
- number of interventions to save a life over 11 years,16 years etc.

2.2 General feedback on the draft flowcharts

Recommended change: clarity on the formatting of the draft flowcharts

The flowcharts currently use both solid and dotted borders and arrows. It is not clear why this is the case and what the difference is between these two formats. The inclusion of a description or key would be helpful for readers.

2.3 Flowchart 1: Risk assessment for the early detection of prostate cancer in Australia (page 12)

Recommended addition: include the PSA cut off limits for each patient group

The cut off limits for each patient group as part of this flowchart could be emphasised. For example, include 'PSA ≥3 µg/L' in the textbox for 50-69 year old males'PSA ≥5.5 µg/L' in the textbox for males 70 years and over. This clarifies to readers that cutoffs are different depending on the testing situation.

2.3 Flowchart 2: PSA testing of 50-69 year old males in the primary care setting (page 12)

Recommended addition: include a second text box to reflect a patient who decides they do not need to have testing at this time

Flowchart 2 should include a second arrow from 'initiate discussion and decision support about benefits and possible harms of testing' leading to a second text box, 'patient decides to not have PSA testing at this time' (our feedback in Section B on Decision Support recommends include this information as part of the decision support resources). This addition will better reflect the shared decision making process for these men, as the decision to not have testing is also an option.

2.4 Flowchart 3: PSA testing of males 70 years and over in the primary care setting (page 13)

Recommended change: make changes to flowchart to reflect the decision to discontinue testing

The text box with <5.5 µg/L Flowchart 3 needs to be clearer and include a symbol that says '*further testing may be discontinued as prostate cancer specific mortality at 15 years is <2% if PSA is <5.5 µg/L*.' In the flowchart, the arrow leading from this textbox suggests undertaking repeat testing cycle, whereas the default in this case should be to discontinue testing (see our feedback on Decision Support for the suggestion to include this as part of the decision support resources).[6] The flowchart should be changed as it may otherwise be confusing for readers.

2.5 Flowchart 6: PSA testing of Aboriginal and Torres Strait Islander males (priority population) in the primary care setting.

Recommended change: amend the flowchart according to the changes recommended by the RACGP under Question 5, Section C: Priority populations.

Flowchart 6 should include a sentence about the importance of downstream access to services for this population.

2.6 What has changed? (pages 35-44)

Recommended addition: a list of screening tests that will be a change in practice

We recommend listing the screening tests that will be a change in practice from the previous guidelines, for example, the free-to-total ratio. This would provide clarity particularly as the MBS expects the use of the free-to-total test in certain situations (such as items 66659 and 66660), so a short statement on why this is no longer recommended should be included.

3. Do you have any feedback on Section A: Risk assessment?

3.1 Family history of prostate cancer (page 47)

Recommended addition: clarity on age of diagnosis of second degree relatives

Recommendation 1.1.3 states that '*Males should be considered at higher risk of prostate cancer mortality for the purposes of PSA testing if two or more second degree relatives (uncle, grandfather, etc.) were diagnosed with prostate cancer.*' This recommendation should be clear about whether men are at higher risk if their second degree relatives were diagnosed with prostate cancer before 65, or if they were diagnosed at any age.

3.2 Other risk factors (page 60)

Recommended addition: possible risks associated with exogenous anabolic steroids for the risk of prostate cancer

Men who take exogenous anabolic steroids (prescribed and not-prescribed) may not be at higher risk of prostate cancer, but these may stimulate prostate cancer growth.[7,8]

4. Do you have any feedback on Section B: Decision support?

4.1 General feedback on Section B: Decision support (pages 61-64)

Recommended addition: information for other decision scenarios

Information on decision support should be included for other scenarios, including:

- Asymptomatic men who decide to not have testing that this time – including what information they should be given, when they should consider returning etc.
- Deciding to discontinue testing, particularly in healthy men aged 70 and over - healthy men aged 70 and over with PSA less than 1.5ng/ml are unlikely to benefit from further screening with PSA.[6] Guidance on making a shared decision to discontinue testing for these patients will be extremely helpful for GPs and their patients.

5. Do you have any feedback on Section C: Priority populations?

5.1 Priority populations, Aboriginal and Torres Strait Islander males (page 66)

Recommended change: clarify key message 3.1.1 as this is confusing for readers

Key message 3.1.1 states PSA testing for Aboriginal and Torres Strait Islander males should be embedded as part of the annual health assessment. This could confuse guideline readers as it suggests annual testing is required. A qualifying statement should be included to clarify this should only be done every two years.

Recommended change: change the start screening age for Aboriginal and Torres Strait Islander men to 50 in line with non-Indigenous men

The RACGP has major concerns with the recommendation to start screening at age 40 for all Aboriginal and Torres Strait Islander men.
The RACGP and NACCHO guideline, National guide to preventive healthcare for Aboriginal and Torres Strait Islander people (the National guide), recommends screening for Aboriginal and Torres Strait Islander men from age 40 only if they are at increased risk (for example, a first-degree family member with cancer diagnosed at age <60 years). The National guide and Red book Both guidelines acknowledge the disparity in mortality rates but do not suggest that Aboriginal and Torres Strait Islander men are at higher risk of developing prostate cancer than non-Indigenous men. However, it appears on the limited evidence available, variations in access to, and engagement with, the health system is a likely reason for the differences in prostate cancer outcomes.[9-11]
The evidence cited in the draft guideline shows no significant difference in the age of diagnosis or spread of disease at diagnosis in Aboriginal and Torres Strait Islander men. Therefore, while they are a priority population, the RACGP is concerned this approach may lead to more unintentional harms for Aboriginal and Torres Strait Islander men, such as false positive PSA tests and overdiagnosis.

The RACGP recommends the draft guideline recommendations for Aboriginal and Torres Strait Islander men align with the National guide chapter on prostate cancer. The National guide also provides helpful information in the Health Impacts of Racism chapter about the impact of using Aboriginal and Torres Strait Islander status as a risk factor for disease.

6. Do you have any feedback on Section D: Early detection?

6.1 Primary health care setting – PSA testing (page 78)

As key providers of prostate cancer testing in the primary care setting, the RACGP provides comments on all of the recommendations put forward by the PCFA in this section.

Recommendation 5.1: no recommended change

This is in line with the RACGP Red book recommendations.

Recommendation 5.2: no recommended change

This is in line with the RACGP Red book recommendations.

Recommendation 5.3: reconsider the wording and strength of recommendation 5.3

The PCFA should reconsider the recommendation strength and wording, similar to the cautious wording in the Red book[12],
'For men aged 50–69 years at average risk of prostate cancer who have been informed of the benefits and harms of testing and who decide to undergo regular testing for prostate cancer, offer PSA testing every 2 years, and offer further investigation if total PSA is greater than 3.0 ng/mL.'*

Prostate cancer screening is recommended to be decided as part of a shared decision making process between GP and patient. Some asymptomatic men make a considered decision to not undertake prostate cancer screening. According to the NHMRC[13], conditional recommendations are interpreted as:
"Most informed people would choose the recommended option but a substantial number would not. Shared decision making is needed to ensure that those receiving care can make an informed values-based choice."

The PCFA should consider rewording the recommendation and reconsidering the recommendation strength to better reflect the shared decision making involved as part of the screening process.

Recommendation 5.4: no recommended change

Recommendation 5.5: RACGP recommends changes to this recommendation

Please see Aboriginal and Torres Strait Islander recommendations above.

Recommendation 5.6: no recommended change

This is in line with RACGP Red book recommendations.

Recommendation 5.7: RACGP recommends changes to this recommendation

It is important men of this age are fully informed and undertake a shared decision making process with their GP. This is particularly the case given men of this age at average risk may be at higher risk of overdiagnosis and harms, so they need to think very carefully before undertaking testing.

The PCFA needs to make it clear this is not a recommendation for testing to be routinely proactively offered to men in their 40s, but is meant to allow GPs some flexibility on start age for highly intrinsically motivated younger men, and emphasise this is a consensus recommendation. Readers may misinterpret this recommendation, particularly if it is going to be promoted to men as part of the implementation process. We would also appreciate clarity as to the source of the evidence for the 1.0mcg/L threshold.

Recommendation 5.8: RACGP recommends additional information be added to this recommendation

Recommendation 5.8 and 5.9 state testing decisions with men aged over 70 should be subject to a 'clinical assessment'. Readers will need more clarity on what 'clinical assessment' means. We provide the following wording as a suggestion:

> "*Offer males aged 70 years and over a PSA test every two years subject to clinical assessment, including life expectancy, comorbidities, and patient values and preferences".*

Recommendation 5.9: RACGP recommends additional information to be added to this recommendation

Provide further context for 'clinical assessment' as above.

Key message 5.10: RACGP recommends additional information to be added to this recommendation

RACGP recommends men are asked to speak with their GP about their individual risk factors and about the benefits and potential harms of screening. We recommend any promotion of testing for men interested in prostate health be careful – particularly if they are at average risk and are at higher risk of harms from overdiagnosis. Incautious promotion may have the effect of making testing appear routine for men in their 40s, which is neither evidence-based nor in the spirit of recommendation 5.7.

7. Do you have any feedback on Section E: Management – Active surveillance?

The RACGP has no recommended changes for this section.

8. Do you have any feedback on Section E: Management – Watchful waiting?

The RACGP has no recommended changes for this section.

9. Do you have any feedback on Section F: Guideline implementation and monitoring?

9.1 Potential barriers to implementation in the Outer Setting (page 169)

Recommended addition: MRI/urology availability and geographic disadvantage

An additional potential barrier to implementation in regional, rural and remote areas of Australia is access to MRI and urologists. This is particularly the case if many men outside of the 50-69 year age group are referred to these services. Many patients in these areas need to travel long distances to access these services and may increase waiting lists for people in these areas.
The PCFA could consider adding information that GPs should be able to order Medicare-rebated prostate MRIs within the current criteria for these tests. At present, such MRI rebates are limited to when the tests are ordered by urologists or oncologists (see item 63541). Allowing GPs to order these tests may reduce the travel and financial burden involved in having to see a urologist.

9.2 Priority population: Aboriginal and Torres Strait Islander males (page 180)

Recommended addition: another recommendation that emphasises the need for greater support for downstream resources and services for Aboriginal and Torres Strait Islander men who have been diagnosed with prostate cancer

As per our feedback for Section C: Priority populations, limited available evidence suggests that variations in access to, and engagement with, the health system is a likely reason for the differences in prostate cancer outcomes for Aboriginal and Torres Strait Islander men.
An additional recommendation should be made for greater investment in implementation measures, such as care pathways, particularly for men living in rural and remote areas, to support them in their cancer journey. Messaging and shared decision making tools should be culturally appropriate and community-led.

9.3 Consistent public messaging from all project collaborators

The RACGP expects all collaborators involved in this project will communicate the guidance with the same main messages as provided in the final revised guideline.
All messaging and communications on prostate cancer screening will need to adhere to and not exceed what is published in the guidelines.

10. Do you have any feedback on Section G: Emerging evidence and future research priorities?

The RACGP has no recommended changes for this section.

11. Do you have any feedback on the Appendices, References or Resources and useful links?

The RACGP has no recommended changes for this section.

12. Do you have any specific feedback on the approaches to early detection of prostate cancer for Aboriginal and Torres Strait Islander males outlined in the DRAFT 2025 Guidelines?

Our response to this question is covered under question 5.1. We recommend the PCFA provides a link to the RACGP & NACCHO National guide to preventive healthcare for Aboriginal and Torres Strait Islander people, as part of cultural considerations. In particular, the Health Impacts of Racism chapter provides a helpful overview of cultural safety and trauma informed care, addressing institutional racism, asking about racism in screening tools and health assessments and understanding the impact of using Aboriginal and Torres Strait Islander status as a risk factor for disease.

13. Throughout these Guidelines, we have endeavoured to use culturally appropriate, respectful and inclusive language that reflects the diverse Australian community and is accessible to all. Do you have any specific feedback on the language used in these Guidelines?

The RACGP has no additional suggestions.

14. Do you have any additional suggestions for how we can ensure these Guidelines are as widely used as possible?

The RACGP has no additional suggestions.

15. Are there any additional areas of emerging evidence and/or future research priorities that should be considered? (Please provide links alongside your feedback)

The RACGP has no additional areas of emerging evidence and/or future research priorities for consideration.

16. Are the DRAFT 2025 Guidelines clear and easy to understand?

The RACGP has no additional suggestions.

17. Is there anything further that needs to be considered for the Guidelines?

17.1 Terminology: General practitioners and specialists (page viii)

Recommended change: change wording throughout the document from GPs to specialist GPs

This change will reflect the acknowledgement on page viii that general practice is a speciality in its own right, requiring specific training and skills.

18. Are there any other comments you would like to make about the DRAFT 2025 Guidelines?

18.1 National screening register

The RACGP recommends consideration of the development of a national registry for prostate cancer screening after shared decision making, aligned with the other Australian screening programs. This will help avoid duplication of testing for patients who see multiple providers, as a central system will capture people who move to a different GP and/or clinic, and allow GPs to undertake the recalls and reminders for screening.

19. Do you consent to PCFA publishing your submission on our website?

Yes, PCFA may publish our submission on the PCFA website.

The RACGP thanks the PCFA again for the opportunity to provide comment on the *Draft 2025 Clinical Guidelines for the Early Detection of Prostate Cancer*. If you have any questions regarding our submission, please contact Mr Stephan Groombridge, National Manager, e-health, Quality Care & Standards at stephan.groombridge@racgp.org.au or 03 8699 0544.

Yours sincerely

Prof Mark Morgan
Chair, RACGP Expert Committee – Quality Care

References

1. Australian Institute of Health and Welfare. The health of Australia's males [Internet]. Canberra: Australian Institute of Health and Welfare, 2023. Accessed 12 May 2025. Available at: https://www.aihw.gov.au/reports/men-women/male-health.
2. Schröder FH, Hugosson J, Roobol MJ, et al. Prostate-cancer mortality at 11 years of follow-up. N Engl J Med. 2012, Mar 15;366(11):981-90. doi: 10.1056/NEJMoa1113135. Erratum in: N Engl J Med. 2012 May 31;366(22):2137.
3. Hugosson J, Roobol MJ, Månsson M, et al. A 16-yr Follow-up of the European Randomized study of Screening for Prostate Cancer. Eur Urol. 2019, Jul;76(1):43-51. doi: 10.1016/j.eururo.2019.02.009.
4. Gulati R, Mariotto AB, Chen S, et al. Long-term projections of the harm-benefit trade-off in prostate cancer screening are more favorable than previous short-term estimates. J Clin Epidemiol. 2011, Dec;64(12):1412-7. doi: 10.1016/j.jclinepi.2011.06.011.
5. Caruana M, Gulati R, Etzioni R, et al. Benefits and harms of prostate specific antigen testing according to Australian guidelines. Int J Cancer. 2024, Feb 15;154(4):648-658. doi: 10.1002/ijc.34731.
6. Vickers AJ, Sjoberg DD, Ulmert D, et al. Empirical estimates of prostate cancer overdiagnosis by age and prostate-specific antigen. BMC Med. 2014, Feb 11;12:26. doi: 10.1186/1741-7015-12-26.
7. van de Ven K, Eu B, Jackson E, et al. GP Guide to harm minimisation for patients using non-prescribed anabolic-androgenic steroids (AAS) and other performance and image enhancing drugs (PIEDs). 2020, Sydney, Australia: Sydney North Health Network (SNHN).
8. Michaud J, Billups K, Partin A. Testosterone and prostate cancer: an evidence-based review of pathogenesis and oncologic risk. Ther Adv Urol. 2015, Dec;7(6):378-87. doi: 10.1177/1756287215597633.
9. National Aboriginal Community Controlled Health Organisation and The Royal Australian College of General Practitioners. National guide to preventive healthcare for Aboriginal and Torres Strait Islander people: Recommendations. 4th edition. East Melbourne, Vic: RACGP, 2024.
10. Adams M, Gleeson K, Supramaniam R, Earnshaw T. Engaging Aboriginal and Torres Strait Islander communities in prostate cancer health care programs. Prostate Cancer Foundation of Australia, 2015
11. Navin Richards J. Engaging Aboriginal and Torres Strait Islander males. Healthy Male; Andrology Australia. 2013
12. The Royal Australian College of General Practitioners (RACGP). Guidelines for preventive activities in general practice. 10th edn. East Melbourne, Vic: RACGP, 2024.
13. NHMRC. Guidelines for Guidelines Handbook. National Health and Medical Research Council. Available at: www.nhmrc.gov.au/guidelinesforguidelines